Vitalograph®

Precision Syringe

Service Manual

www.distrimed.com

CE
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Calibration, service and repairs should be carried out only by the manufacturer, the approved importer or by Service Agents specifically approved by Vitalograph. There are no user serviceable components inside the equipment.

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Introduction

The Precision Syringes manufactured by Vitalograph are intended to be used for checking the accuracy and linearity of Vitalograph Spirometers. They can also be used to calibrate Vitalograph Spirometers if they have been calibrated to a standard reference and are within calibration date. They are manually operated devices that conform to accuracy requirements specified by the American Thoracic Society.

Description of Syringe

The syringes consist of a cylinder with an internal piston and piston seal, end plates, a handle and support rods. The piston is connected to the piston rod with a plastic knob for manual operation.

1-Litre Syringe

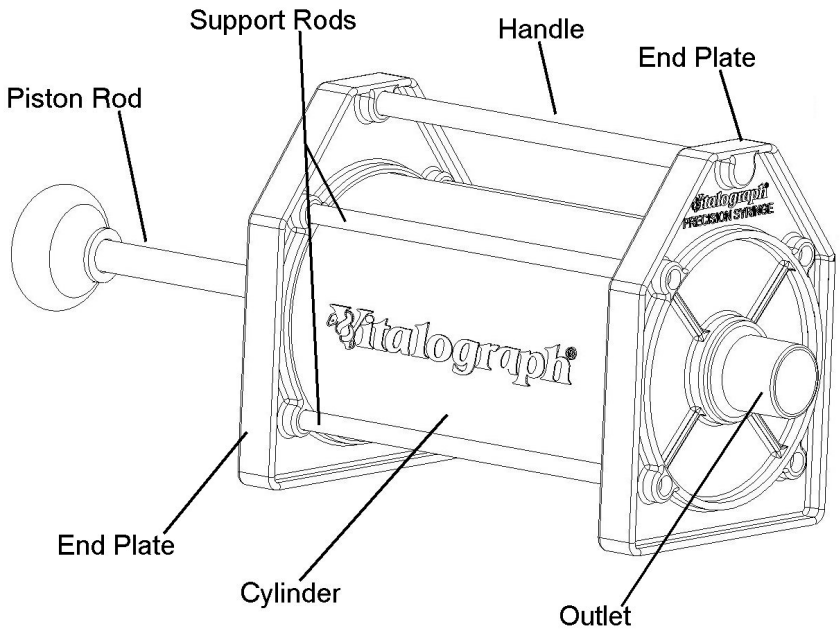

FIGURE 1: MAIN COMPONENTS OF 1-LITRE SYRINGE

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3-LITRE SYRINGE

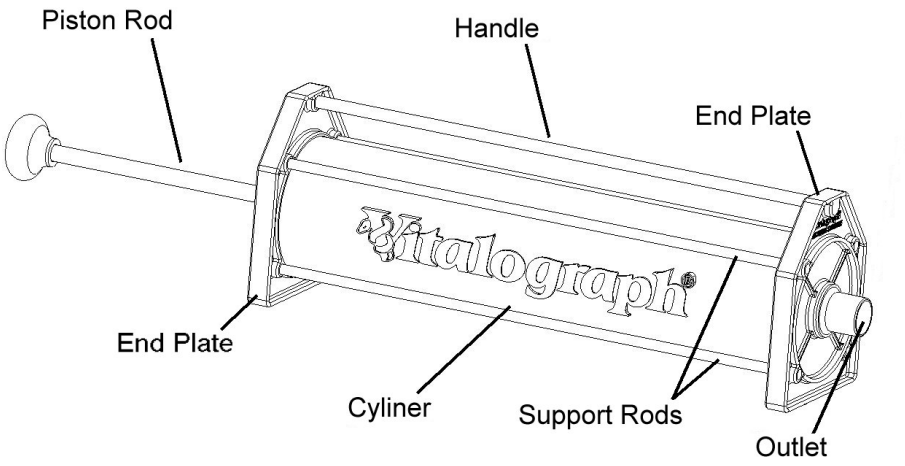

Figure 2: Main Components of 3-Litre Syringe

Performing a Test

The syringes are operated by actuating the piston rod in and out of the cylinder assembly with the outlet port attached to the device under test. When actuated, the syringes displace known volumes of air into the flow device. Accuracy is determined by comparing the volume of the calibration syringe with the volume displayed on the flow measurement system of the connected device.

Cleaning Instructions

The syringes are supplied clean and non sterile. Non-critical equipment should be kept visibly clean using mild detergent (neutral pH 7), soap with tap water or standard hospital disinfectant/cleaners. Clean soft cloths should be used for wiping and drying. Cleaning solutions or cloths should not be used inside the cylinder area of the syringe. Disinfection or sterilisation is not required because the syringe will not come into contact with patients.

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Technical Specifications

1 Litre Syringe

Volume Measurement	1L
Measuring Accuracy	0.5%
Operating Temperature	15–40°C
Safety Standards	Medical Devices Directive 9342/EEC
Gross Size	300mm x 170mm x 125 mm
Gross Weight	2.5kg
Storage Temperature	0–50°C
Storage Relative Humidity	10%–95%

3 Litre Syringe

Volume Measurement	3L
Measuring Accuracy	0.5%
Operating Temperature	15–40°C
Safety Standards	Medical Devices Directive 9342/EEC
Gross Size	500mm x 170mm x 125 mm
Gross Weight	2.5kg
Storage Temperature	0–50°C
Storage Relative Humidity	10%–95%

MAINTENANCE

A routine annual service and calibration certification on the syringes is strongly recommended. The equipment used to perform the accuracy check should itself be certified and traceable to national or international standards.

Calibration, service and repairs should be carried out only by the manufacturer, the approved importer or by Service Agents specifically approved by Vitalograph. There are no user serviceable components inside the equipment.

For the names and addresses of approved Vitalograph Service Agents, please contact any of your local Vitalograph distributors.

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Repairs and Spares

Consumables/Accessories

1Litre Syringe Spares

Description	Cat. No.
Cylinder Seal	32312spr
Front End Plate O-Ring	32313spr
Calibration Screw	33275
Lock screw	33276
Neoprene feet 4 pack	32494spr
Stroke setting tool	36110
Piston with valve	36081spr
Front end plate	36089spr
Molykote 111 silicone grease	32254spr

3Litre Syringe Spares

Description	Cat. No.
Cylinder Seal	32312spr
Front End Plate O-Ring	32313spr
Calibration Screw	33275
Lock screw	33276
Syringe End Plate	36118
Stroke setting tool	36129
Molykote 111 silicone grease	32254spr

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Calibration of Precision Syringe

Equipment Required:

Description	Vitalograph reference
3mm AF Allen Key	
1-Litre Syringe Stroke Setting Tool	36110
3-Litre Syringe Stroke Setting Tool	36129

Note: The Stroke Setting Tool should always be located on the first stepped face of the knob, nearest the shaft.

1. Push piston of syringe in fully.
2. Unscrew the spring loaded, clearance setting part of syringe Stroke Setting Tool.
3. Place spring-loaded clearance setting part of tool between the underside of the syringe operating knob and the end plate. Unscrew thumb lock and allow spring action to adjust length until it is a close fit between knob and end plate. Lock again with thumbscrew.
4. Screw clearance setting part onto setting rod, making sure it is fully home.
5. Withdraw the syringe piston to its full limit.
6. Place complete tool between the operating knob and the end plate. Compare clearance between the operating knob and the end plate with the Stroke Setting Tool.

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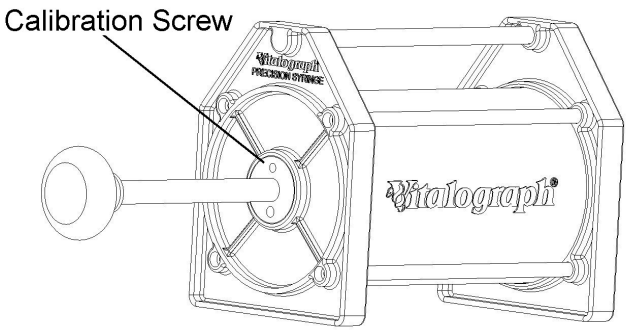

Figure 3: Location of the Calibration Screw in the 1-Litre Syringe

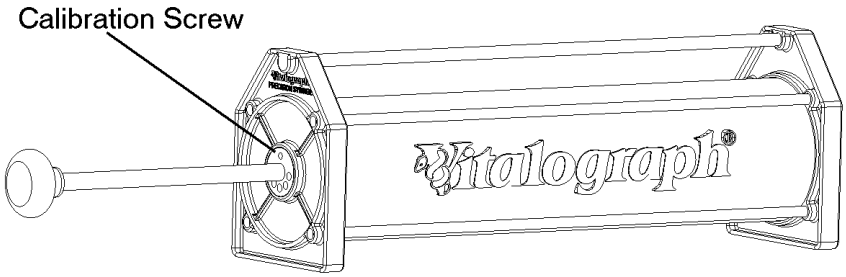

Figure 4: Location of the Calibration Screw in the 3-Litre Syringe

To adjust the stroke setting of the syringe, the following procedure must be carried out:

1. Remove the locking set screw to obtain access to the calibration screw, which is positioned adjacent to the piston rod.

2. Insert a 3.0mm AF Allen key and adjust as required. Turning the screw clockwise shortens the stroke, anti-clockwise increases stroke.

3. When the correct stroke is achieved, lock the calibration screw firmly with the locking setscrew.

Finally check that the Stroke Setting Tool just fits between the operating knob and the end plate, with the piston fully withdrawn.

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DECLARATION OF CONFORMITY

Product: Vitalograph® Precision Syringe

Vitalograph hereby ensures and declares that the above product associated with this manual, is designed and manufactured in accordance with the following QMS regulations and standards:

- European Medical Devices Directive {MDD} 93/42/EEC.
  This device, classified as 2a as per Annex IX of MDD 93/42/EEC, meets the following provisions of Annex II of the Medical Devices Directive as per Article 11, section 3a, excluding point 4 of Annex II.

CE 0086

- Canadian Medical Device Regulation {CMDR}
- FDA Quality System Regulation {QSR} 21 CFR 820.
- EN ISO 13485: 2003. Medical devices. Quality management systems. Requirements for regulatory purposes.

Certifying Body {for 93/42/EEC and CMDR}: British Standards Institute {BSI}

Certificate Nos. CE 00772, MD 82182, FM 83550

Signed on behalf of Vitalograph (Ireland) Ltd.

B. R. Garbe.
Group Managing Director

This Manual is intended for use only by suitably qualified medical device technicians, who have been trained on the procedures in this manual.

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Guarantee

Terms of Guarantee

Subject to the conditions listed below, Vitalograph Ltd. and its associated companies, (hereinafter called the Company) guarantee to repair or at its opinion replace any component thereof, which, in the opinion of the Company is faulty or below standard as a result of inferior workmanship or materials.

The conditions of this Guarantee are:

1. This Guarantee shall only apply to hardware defects which are notified to the Company or to its accredited distributor within 1 year of the date of purchase of the equipment, unless otherwise agreed in writing by the Company.
2. This Guarantee does not cover any faults caused by accident, misuse, neglect, tampering with the equipment, use of consumable items or parts not approved by the Company, or any attempt at adjustment or repair other than by personnel accredited by the Company, nor does it cover reinstatement of any configuration changes caused by the installation of any software.
3. If a defect occurs, please contact the supplier from whom it was purchased for advice. The Company does not authorise any person to create for it any other obligation or liability in connection with Vitalograph® equipment.
4. This guarantee is not transferable and no person, firm or company has any authority to vary the terms or conditions of this Guarantee.
5. To the maximum extent permitted by law, the Company does not accept liability for any consequential damages arising out of the use of, or inability to use any Vitalograph® equipment.

This Guarantee is offered as an additional benefit to the Consumer's statutory rights and does not affect these rights in any way.

FDA Prescription Legend

FDA Notice
Caution: Federal Law restricts this device to sale by, or on the order of a physician.

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No: PPM

Planned Preventive Maintenance Service

Calibration Syringe Service Schedule

Serial No:	[[Cal Syringe SNo]]
Manufacturer:	
Model:	

PRE SERVICE REPORT

- ☐ Record of Pre-Service Condition
- ☐ Accuracy - +/- 0.5% Yes/No

DIS-ASSEMBLE

- ☐ Piston
- ☐ Piston Valve
- ☐ Piston Seal
- ☐ Piston Shaft & Secure
- ☐ Piston Shaft Handle

Check for condition & wear of all components as. listed above

- ☐ All components cleaned & lubricated as necessary

FRONT END PLATE

- ☐ Front End Plate Nozzle
- ☐ Front End Plate Valve
- ☐ Front End Plate 'O' ring

REAR END PLATE

- ☐ Rear End Plate Sleeve
- ☐ Rear End Plate Adjusting Grub Screw
- ☐ Rear End Plate Anti-Tamper Grub Screw
- ☐ Set Zero Setting

RE-ASSEMBLY

- ☐ Re-Grease
- ☐ Torque Allen Screws
- ☐ Pressure Check (Leak test)
- ☐ Rubber Feet

FINAL INSPECTION

- ☐ Check Complete Assembly
- ☐ Affix Service Label
- ☐ Affix "Calibration void" label (where applicable)
- ☐ Complete Calibration Certificate

RECORD KEEPING

- ☐ Post Service Accuracy - Tolerance +/- 0.5%
- ☐ Setting Tool No.
- ☐ Reference Calibration Device used:

SPECIAL ADVICE TO USER:

Vitalograph Trained Service Technician:

Name:

Signature: Date:

I hereby Certify this instrumentation to be safe and in proper working order.

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